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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/19,272	05/04/2001	Hiroshi Yamamoto	19036/36959	7004

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	29

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,272	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-39* is/are pending in the application.

4a) Of the above claim(s) *20-26 and 29-39* is/are withdrawn from consideration.

5)☒ Claim(s) *11, and 14* is/are allowed.

6)☒ Claim(s) *1-4,6-10,12,13,15-19,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *22* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Election/Restrictions

Claims 1-4, and 6-39 are pending and claims 20-26, and 29-39 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-4, 6-19, 27, and 28 are examined on merits.

Claim Rejections - 35 USC § 102

Claims 1, 4, 6-10, 12, 13, 15, 19, 27, and 28 remain rejected for reason of record and claim 3 is also rejected under 35 U.S.C. 102(b) as being anticipated by Streuli et al (1992, The EMBO Journal, vol. 11, pages 897-907).

Applicant argues that the various monoclonal antibodies to LAR taught by Streuli et al have specificity to LAR extracellular and/or LAR FN III domains while the instant claims are directed to a monoclonal antibody having specificity to a LAR phosphatase subunit and "specificity" is defined at page 6 line 21 of the instant specification as "antibodies which are specific to a LAR intracellular domain but not to CD45". These arguments are not commensurate with the scope of the instant claims because claim 4, which depends on claim 1, says the full scope claimed by the instant claims are any monoclonal antibody generated by any peptide encoded by SEQ ID NO:1. Sequence search reveals that SEQ ID NO:1 recited in claim 4 encodes the 1897 amino acid protein with the three Ig domains (LAR extracellular) and fight FN III domains as well as the phosphatase domain shown in Fig. 1 of Streuli et al at page 898, the top figure

designated as LAR. Therefore the Office interprets the instant claims as drawn to any monoclonal generated by any peptide sequence generated from a peptide encoded by instant SEQ ID NO:1 and Streuli et al teach several monoclonal antibodies generated from a peptide encoded by instant SEQ ID NO:1, thus anticipating instant claims. As for claim 27, applicant does not argue that the instantly claimed anti-LAR antibody and the antibody of the prior art are different products. Rather applicant argues that the prior art does not teach nexus between LAR and thyroid carcinoma and this argument does not establish the patentable differences between the instantly claimed product and the product of the prior art. The Office interprets the claim read on anti-LAR antibody per se and maintains that the functional characteristics specified in the claim is inherent property of the antibody since the prosecution history appears to indicate that the instantly claimed anti-LAR antibody and the antibody of the prior art are the same product. Further claim 3 is drawn to antibody having specificity to an intracellular domain of a LAR phosphatase subunit, and having no specificity to CD45. Streuli et al teach monoclonal anti-LAR antibody 11.1A, 71.E, 128.4A, and 136.1 that do not bind to CD45 (synonym for LCA). Note Fig. 1 at page 898.

Claim 2 **remain rejected** for reason of record under 35 U.S.C. 102(b) as being anticipated by applicant's admission on page 6 lines 21-24 of the specification.

Applicant argues that the claimed antibodies are specific to LAR phosphatase subunits and thus do not cross-react with CD45. This argument is not commensurate with the scope of the claim because the claim says any monoclonal antibody having

specificity to an intracellular domain of a LAR subunit is within the scope of the claim no matter the monoclonal antibody cross-reacts to CD45 or not.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 13 are confusing because the claims refer to claim 5, which does not exist. For the purpose of this office action, the Office will assume the claims are drawn to anti-LAR antibody. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 6, 27, and 28 are rejected under 35 U.S.C. **102(b)** as being anticipated by Takeuchi et al (1993, IDS filed on 5/3/2001 #C9, Tissue Antigens 42; 441) as evidenced by Streuli et al (cited above).

The claims are interpreted as drawn to monoclonal antibody capable binding specific epitope located at LAR phosphatase subunit. Takeuchi et al teach the AE-6 monoclonal antibody recognizes the epitope, VHCSAGV, which is located in the LAR P subunit. See Fig. 3 for the location of LAR P subunit. As for claims 27 and 28, the

claim is drawn to antibody per se and the functional characteristic is the inherent property of the antibody of the prior art.

Claims 15, and 16 are rejected under 35 U.S.C. **102(b)** as being anticipated by either Ahmad et al (1995, J Clin Invest; 95 :2806-12) or Ahmad et al (1997, J. Biol. Chem. vol. 272, pages 448-457).

The claims are drawn to method of generating an antibody having specificity to LAR P subunit. Ahmad et al (1997) teach method of generating anti-LAR P subunit antibody capable of regulating insulin signal at page 449 under Experimental Procedures and Ahmad et al (1995) also teach method of generating anti-LAR P subunit antibody used in detecting insulin receptor dephosphorylating activity in obese people at page 2807 under Methods. Note use of the antibody in fig. 1-5.

Claim Rejections - 35 USC § 103

If applicant can overcome rejection of the claims under 35 U.S.C. 102(b) above, then claims 1-4, 6-10, 12, 13, 15-19, and 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Ahmed (1995, cited above) or Ahmed (1997, cited above) as applied to claims 15 and 16 above, and further in view of Streuli et al (1992, cited above).

The claims are interpreted as drawn to anti-LAR P subunit antibody. Streuli et al are cited to show the state of art about LAR protein and state of art making monoclonal antibody against a known protein sequence; the whole protein sequence (LAR) has been known and the authors mapped the different protein domains and also determined processing of the precursor to P subunit and E subunit. The secondary reference does

not teach why one in ordinary skill would be motivated to make antibody specific to LAR P subunit. However, either one of the primary reference teaches that LAR P subunit is involved in controlling two important human diseases, namely diabetes and obesity and further teach that there are many different phosphates with similar structures to LAR P subunit but authors in the primary reference conclude LAR P subunit is involved in obesity or diabetes through insulin receptor dephosphorylating activity by the phosphate. Further the three references teach making an immunogen in a host, followed by making either polyclonal or monoclonal antibody using the immogen is well known technology before the effective filing of the instant application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make anti- LAR P subunit antibody with reasonable expectation of success for various useful purposes.

Double Patenting

Claims 1-4, 6-10, 15-19, 27, and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 5-21 of copending Application No. 09/719,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because the antibody (or hybridoma cell producing the antibody) of instant claims 1, 2, and 6-10 binds to LAR phosphatase subunit but the instant claims do not specify whether the antibody cross-react with any other phosphatase with similar structures while the antibody of claims 1, 2, and 5-21 of copending Application No. 09/719,272 binding to LAR phosphatase subunit also cross-reacts with other phosphatases. Instant claim 3

does not cross-react with CD45 but but the claim does not say whether the antibody cross-react with any other phosphatases. As for method of producing antibody capable of binding to LAR phosphatase domain, instant claims 15-19 and claims 17-21 of copending Application No. 09/719,272, the immunogen of instant claim 15 is a species of claim 17 of copending Application No. 09/719,272.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 11, and 14 are allowed.

The indicated allowability of claims 3, 16-18 is withdrawn in view of the above rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
April 29, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

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